C4

37. The method of claim 36, wherein said antibody is introduced into the digestive system of the non-ruminant mammal by orally feeding said antibody to the non-ruminant mammal in a capsule that protects said antibody until the antibody reaches said lower gastro-intestinal tract. --

REMARKS

This Preliminary Amendment is in response to the Office Action mailed February 3, 1999, which included new grounds of rejection and was made Final. This Preliminary Amendment is filed as part of a Continued Prosecution Application, which was filed on August 2, 1999. A Petition for Three Month Extension of Time, with a check for the required fee of \$435.00, was submitted with a Certificate of Mailing on July 29, 1999.

An Affidavit Under 37 C.F.R. § 1.132, signed by Richard Lee Atkinson, Jr., M.D., is submitted herewith. The purposes of the affidavit include demonstrating to the Examiner:

- 1) there has been a long-felt need for an effective method to inhibit lipase in the gastro-intestinal tract;
- 2) the long-felt need for an effective method to inhibit lipase in the gastro-intestinal tract has not been satisfied by the prior art;
- 3) the long-felt need for an effective method to inhibit lipase in the gastro-intestinal tract is met by the present invention;
 - 4) those of ordinary skill in the art were skeptical that an

orally fed antibody could be delivered through the digestive system and be effective in the gastro-intestinal tract;

- 5) those of ordinary skill in the art would consider the references cited by the Examiner in the 35 U.S.C. § 103 rejections to be non-analogous art to each other and to the present invention, and would not be motivated to combine them in the proposed manner;
- 6) to express the opinions, and bases therefor, of the affiant Dr. Richard Atkinson, a renowned expert in the relevant art, as to the inapplicability of the references cited by the Examiner to the claims of the present application, in support of the Applicant's position that the claims of the present invention, as amended, are non-obvious.

Consideration of Prior Art

The Applicant respectfully requests the Examiner to consider the references disclosed in the Supplemental Information

Disclosure Statement submitted by the Applicant by Express Mail procedures on January 19, 1999. The references cited therein were first brought to the Applicant's attention in an International Search Report less than three months before January 19, 1999. In the event the Examiner did not receive a copy of the International Search Report, a duplicate copy is provided. If the Examiner requires additional copies of any of the references, please contact the Applicant's undersigned attorney.

35 U.S.C. § 103 Rejections

The Examiner continued to reject claims 1-4, 8, 11, 14, and 17-22 under 35 U.S.C. § 103. The Examiner also rejected claims 25-35 under § 103. Although the references were discussed individually in Applicant's earlier Amendment, the Applicant respectfully submits that without any suggestion to combine the teachings of the references in the manner proposed by the Examiner, it should not be the case that the combination of all of the cited references make up the state of the art with regard to the claimed invention. The accompanying Affidavit of Dr. Richard Atkinson demonstrates that many of the references cited as bases for the Examiner's rejections are from non-analogous art to one another, as well as to the claimed invention. As such, those of ordinary skill in the art would not have so combined the references because they would not have looked to all of the references if faced with the problem presented to the Applicant.

Also, because secondary considerations of nonobviousness, such as long-felt but unresolved need in the art,
support the Applicant's position of non-obviousness, the
Examiner's reconsideration is respectfully requested.

35 U.S.C. § 102

The Examiner rejected Claim 34 under 35 U.S.C. § 102(b) as being anticipated by Murase, et al., Atherosclerosis, 1981, 39:293-300. The Applicant amended claim 34 by inserting -- orally -- before "administering" in line 5. While the Applicant does not concede that HTGL regulates biochemical processes in the

gastrointestinal tract, or that Murase, et al. anticipates claim 34, it is respectfully submitted that this amendment takes claim 34 even further away from the Murase et al. reference.

Murase et al. teach injecting rats with anti HTGL gamma globulin through their cannulated jugular vein. In the present invention, anti-lipase antibodies are orally administered. Oral administration of antibodies intended to be active in the gastrointestinal tract is far different from the injection of anti HTGL gamma globulin through the jugular vein. Thus, it is respectfully submitted that claim 34, as amended, is not anticipated by Murase et al.

Conclusion

In view of the foregoing, as well as the accompanying Affidavit of Dr. Atkinson, the Applicant respectfully requests the Examiner's reconsideration and favorable action. In the event any fees are necessary in order to consider this Preliminary Amendment, please charge our Deposit Account No. 20-1111.

Respectfully submitted,

Date: August 9,1999

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